Cervical Biopsy Correlation of SurePath™ Liquid Based Pap Tests Interpreted as Atypical Squamous Cells of Undetermined Significance in Conjunction with Digene Hybrid Capture II High Risk Human Papilloma Virus Testing

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ABSTRACT

Context: In 2002, the American Society for Colposcopy and Cervical Pathology (ASCCP) introduced new follow-up guidelines for patients with liquid-based Pap tests interpreted as Atypical Squamous Cells of Undetermined Significance (ASC-US) with High Risk (HR) Human Papilloma Virus (HPV) testing.

Objective: To determine if SurePath™ (SP) liquid-based Pap testing with Digene Hybrid Capture 2 (HCII) HR HPV testing increases positive correlations between ASC-US Pap tests and follow-up biopsies over conventional Papanicolaou (Pap) smears alone.

Methods: In June 2003, our laboratory completed 100% conversion from conventional Pap smears to SP Pap testing, adding HCII HR HPV testing for Pap tests interpreted as ASC-US. Prior to this conversion, all patients with ASC-US Pap smears were referred for biopsy follow-up**.**

Design: Biopsy correlations of SP ASC-US Pap tests with HR HCII HPV results, collected from June through December 2003, were compared to conventional Pap smears collected during the same time frame in 2002. In 2003, 458 SP Pap tests were positive for HR HPV, with 278 patient biopsies collected. 814 conventional ASC-US Pap tests were collected in 2002, with 479 biopsies collected.

Setting: A retrospective review of statistical data performed by the cytology department.

Main Outcome Measures: Percentage of patients referred for cervical biopsy, percentage of CIN detected on cervical biopsy, and percentage of biopsies diagnosed as No Evidence of Dysplasia (NED).

Results: Patients referred for colposcopic biopsy decreased by 25.92 % from 2002 to 2003 with a 17.27% increase in CIN detection and a 21.31% reduction of biopsies diagnosed as NED.

Conclusion: SurePath™ liquid-based Pap testing with Digene HCII HR HPV™ testing has decreased the overall number of patients referred for colposcopy, while increasing CIN detection on biopsy and decreasing the percentage of biopsies diagnosed as NED. This change has provided a more effective method of screening our patients for cervical disease than conventional Pap testing alone.

ASC-US FOLLOW UP DATA	2002 Conventional	2003 Surepath
Total Paps Reviewed June-December	30724	26975
Total ASC-US Paps	814 (2.65%)	844 (3.13 %)
ASC-US with No HPV Testing	814	11 (1.30%)
ASC-US with HR HPV (-)	0	375 (44.43%)
ASC-US WITH HR HPV (+)	0	458 (54.27%)
Follow Up Biopsies	479 (58.85%)	278 (32.93%)
Follow Up Paps	229 (28.13%)	34 (7.42%)
No Follow Up	106 (13.02%)	146 (31.88%)

SUMMARY RESULTS

SurePath™ liquid-based Pap testing with Digene HCII HR HPV™ testing:

Increased CIN detection on biopsy by 17.27%

Decreased the percentage of patients referred to colposcopy by 25.92% (32.93% in 2003, compared to 58.85% in 2002)

Decreased the percentage of biopsies interpreted as No Evidence of Dysplasia (NED) by 21.31%

Increased positive biopsy correlation by 22.33% (67.63% in 2003 from 45.30% in 2002)

Based on these results, SurePath™ liquid-based Pap testing with Digene HCII HR HPV™ testing has provided a more effective method of screening our patients for cervical disease than conventional Pap testing alone.

FOLLOW UP BIOPSY RESULTS

Biopsy Results	2002 Conventional	2003 Surepath	Percent Change
NED	*252 (52.61%)*	*87 (31.29%)*	*-21.32*
HPV/ Condyloma	121(25.26%)	85 (30.57%)	5.31
CIN 1	71 (14.82%)	69 (24.82%)	10
CIN 2	13 (2.71%)	10 (3.60%)	0.89
CIN 1-2	3 (0.63%)	9 (3.24 %)	2.61
CIN 3	2 (0.42%)	7 (2.52 %)	2.1
CIN 2-3	4 (0.84%)	7 (2.52 %)	1.7
CIN Total	*93 (19.42%)*	*102 (36.69%)*	*17.27*
VAIN 1	1 (0.21%)	0	-0.21
ADCA	2 (0.42%)	1 (0.36%)	-0.06
Insufficient	10 (2.09%)	3 (1.08 %)	-1.01
Positive BX Correlation	*217 (45.30%)*	*188 (67.63%)*	*22.33*

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